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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,421	01/22/2001	Michael J. Shamblott	JHU1750-1	9551

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/767,421	SHAMBLOTT ET AL.	
	Examiner	Art Unit	
	Deborah Crouch	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,11,13,15,16,22,23,25-29,32 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,13,15,16,22,23,25-29,32 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *January 22, 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 6, 2009 has been entered. The after-final amendment filed January 6, 2009 has been entered and considered. However, applicant's arguments are not persuasive. Claims 1, 10, 13, 15, 16, 22, 23, 25-29, 32 and 35-37 are pending. The term "EBD-derived cell" means an undifferentiated cell that composes an embryoid body.

The rejection of claims 22, 23, 25-29, 32 and 35-37 under 35 U.S.C. § 103 in the office action mailed August 6, 2009 because Hogan does not teach enzymatic digestion of EB's prior to plating, nor does Hogan teach media comprising less that 15% serum. Further such teaches were absent from the art at the time of filing. For these reasons claims 22, 23, 25-29, 32 and 35-37 are free of the prior art at the time of filing.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 23, 25-29, 32 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").Without adequate description, the skilled artisan cannot envision fibroblast as part of applicant's invention.

"[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." In re Barker, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1566,

43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). "The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). Further, the written description requirement promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term. Without such a written description, the specification fails to convey to the skilled artisan at the time of filing possession of the claimed invention.

Claim 22 states "media containing less than 15% serum." However specification support for the phrase cannot be found (specification, page 15, parag. [0053], lines 5-11 and page 68, parag. [0183], lines 3-6). The specification cites ranges of serum concentration (%) that include both values above and below 15%, but there is no contemplation of "less than 15% serum." Applicant has not shown possession by words, disclosure, structure or drawings. Therefore applicant has not conveyed possession of the claimed invention at the time of filing.

The phrase should either be removed from claim 22 or applicant should provide specific support for this concept.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10, 13, 15, 16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,453,357 issued September 26, 1995 (Hogan) in view of Shamblott et al (1998) Proced. Natl. Acad. Sci. 95, pp. 13726-13731 (ref. AE) for reasons set forth in the office action mailed August 6, 2008...

Hogan teaches mouse embryoid body-derived cells (EBD) produced by plating mouse embryoid bodies on tissue culture plastic (col. 8, lines 42-45). The EBD cells are described as rapidly attaching to the plastic and give rise to a variety of cell types, including endoderm, spontaneously contracting muscle, nerve and endothelial cells, and fibroblast like cells (col. 8, lines 45-49). Hogan describes the picking of single clones of mouse ES cells to, indicating clonal selection from a single EB-derived cell (col. 8, lines 5-9). These cell lines were then used to produce EBD cells in vitro. Further, the specification does not provide guidance as to characteristics of the claimed clonal EBD cells that would distinguish from the EBD cells of Hogan. Hogan offers additional motivation in stating derivatives of human ES cells, produced by the method disclosed therein, EBD-cells are a derivative of ES cells, could treat neurodegenerative disease (col. 5, lines 32-34). It is noted Hogan describes the EBD cells produced to contain a

population of nerve cells. Hogan further teaches that LIF may not be required for the maintenance of ES cells, which are interpreted to be the cells of the claims (col. 4, lines 55-67). As a distinction between the claimed EBD's and those of Hogan cannot be seen, the characteristics of the EBD cells claimed would reasonably be expected to be present in Hogan's EBD cells.

Shamblott teaches embryoid bodies (EB's) produced from human primordial germ cells were plated into tissue culture plates in the absence of LIF (hPGC's) (13727, col. 1, parag. 2). After culture for 14 days, the EB's were shown to have developed into a variety of cell types – muscle, neurofilament (page 13729, Table 1).

As the presently claimed EBD cells are derived from human primordial germ cells, the ordinary artisan at the time of filing would have reasonably expected the physiological characteristics to be the same for the claimed cells and those of Hogan even given species differences. Thus, the cells of Hogan in view of Shamblott undergo at least 30 population doublings, proliferate under culture conditions lacking LIF, a fibroblast feeder layer, or both, and transfectable with a retrovirus, lentivirus or both. There is no evidence to the contrary on the record. Products obvious over those in the art would be expected to have the same properties absent evidence to the contrary. It is noteworthy that the EBD cells claimed have been shown to consist of a variety of differentiated cell types just as the EBD cells of Hogan. This adds even more evidence that the EBD cells of the claims and those of Hogan in view of Shamblott are obvious. the ordinary artisan would have been motivated to produce human EBD cells as taught by Hogan in view of Shamblott to provide a source of lineage restricted cells for

transplantation studies or developmental/differentiation research.

Therefore at the time of the present invention, it would have been obvious to produce human EBD-cells in view of the production of mouse EBD-cells as taught by Hogan in view of Shamblott teachings human EB's. The prior art offers the requisite teachings, suggestions and motivation to combine, and a reasonable expectation of success.

Applicant argues the Examiner has mischaracterized Hogan. It is true the passage cited in the previous office action is incorrect. Applicant is now directed to the proper cite in Hogan where EBD cells are produced and characterized. As to the argument that applicant's cells are capable of long-term culture, there is no evidence that human EBD's produced according to Hogan in view of Shamblott would not also culture in a prolonged fashion. The EBD cells of Hogan were produced without feeder cells. The lack of hEBD cells not requiring LIF for proliferation is found in Shamblott culturing EG cells in the absence of LIF and obtaining EB's which inherently contain EBD cells. No evidence is of record that the mouse EBD cells of Hogan are not capable of long-0term culture. While such arguments have been made, they aren't persuasive because they aren't supported by a declaration under 35 U.S.C. § 1.132 or other direct evidence. Further, even if the mouse EBD cells of Hogan do not meet the characteristics claimed, they don't need to. Hogan is used for the teachings of producing mouse EBD cells, but Hogan also teaches the production of hES cells using the same method as mES cells. Thus Hogan in view of Shamblott is the rejection. Why wouldn't following Hogan's disclosure but using human EG's to produce human EBD

cells as taught by Shamblott lead to the claimed EBD cells? Applicant has not answered this question.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (571)272-0727. The examiner can normally be reached on M-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

May 26, 2009